

Remarks/Arguments

Applicants have received and carefully reviewed the Office Action mailed October 6, 2009. Currently, claims 1-9, 15, 21, 22, 24-38, 51-62, and 65-66 have been rejected. In this amendment, claim 62 has been amended and new claim 67 has been added. As such, claims 1-9, 15, 21, 22, 24-38, 51-62, and 65-67 remain pending. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 102

In paragraph 3 of the Office Action, claim 62 was rejected under 35 U.S.C. 102(b) as being anticipated by Alba et al. (U.S. Patent No. 5,634,901). After careful review, Applicants respectfully disagree. Claim 62 recites:

62. (Currently Amended) A catheter assembly comprising:
a catheter shaft;
a balloon, the balloon arranged on the catheter shaft and having at least a first tapered end and a second tapered end; and
a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the balloon, the rotatable sheath including a first radially tapered end that is arranged in radial alignment with the first tapered end of the balloon and a second tapered end that is arranged in radial alignment with the second tapered end of the balloon, the first radially tapered end of the rotatable sheath being configured to complement the first tapered end of the balloon, the second tapered end of the rotatable sheath being configured to complement the second tapered end of the balloon, wherein the first and second tapered ends being configured to complement the first and second tapered ends of the balloon ~~limit~~ longitudinally ~~secure displacement of~~ the rotatable sheath relative to the balloon.

Nothing in Alba et al. appear to disclose many elements of claim 62, including for example, “wherein the first and second tapered ends being configured to complement the first and second tapered ends of the balloon longitudinally secure the rotatable sheath relative to the balloon”.

Alba et al. appears to disclose a catheter assembly 2 including a balloon catheter 8 including a catheter shaft 10 and a dilation balloon 12 at the distal end 14 of the catheter shaft. The catheter assembly 2 also appears to include a tubular sleeve assembly 16 slidably mounted over the catheter shaft 10. The tubular sleeve assembly 16 appears to include a tubular, radially expandable, elastomeric enlargement sleeve 18 at the distal end of the sleeve assembly 16. As shown in Figures 1A and 1B, the enlargement sleeve 18 can move from a position proximal of the balloon to a position over the balloon. As such, nothing in Alba et al. appears to disclose

“wherein the first and second tapered ends being configured to complement the first and second tapered ends of the balloon longitudinally secure the rotatable sheath relative to the balloon”, as recited in claim 62.

Notably, MPEP § 2131 states, “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Applicants submit that Alba et al. fails to disclose each and every element of claim 62. Further, there appears to be no reason to modify the teachings of Alba et al. to arrive at the device of claim 62. For at least these reasons, claim 62 is believed to be patentable over Alba et al.

Claim Rejections – 35 USC § 103

In paragraph 6 of the Final Office Action, claims 1, 2, 5-9, and 31-38 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974). After careful review, Applicant must respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Previously Presented) A catheter assembly comprising:
a catheter, the catheter comprising a catheter shaft and a balloon positioned at a distal end portion of the catheter shaft, the balloon including a first portion having a first outer diameter and a second portion having a second outer diameter that is different than the first outer diameter;
a rotatable sheath, the rotatable sheath rotatably disposed about at least a portion of the balloon, the rotatable sheath including a first portion having a first portion inner diameter and a second portion having a second portion inner diameter that is different than the first portion inner diameter, the first portion of the rotatable sheath being arranged axially adjacent the second portion of the rotatable sheath, the first portion of the rotatable sheath arranged in radial alignment with the first portion of the balloon and the second portion of the rotatable sheath arranged in radial alignment with the second portion of the balloon; and
a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to an outer surface of the rotatable sheath.

Nothing in Cox appears to disclose many elements of claim 1, including for example, “the rotatable sheath including a first portion having a first portion inner diameter and a second portion having a second portion inner diameter that is different than the first portion inner

diameter, the first portion of the rotatable sheath being arranged axially adjacent the second portion of the rotatable sheath, the first portion of the rotatable sheath arranged in radial alignment with the first portion of the balloon and the second portion of the rotatable sheath arranged in radial alignment with the second portion of the balloon” or “a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to an outer surface of the rotatable sheath”.

The Office Action initially refers to Figure 22 of Cox as disclosing the rotatable sheath, but then refers to Figure 8 of Cox as disclosing a sheath with tapered ends. Applicants submit that there is no reason to combine these embodiments of Cox as suggested in the Office Action. Figure 22 appears to teach a perfusion adaptor including a ductal sleeve 350 and a positioning member 352. (See column 14, lines 8-9). As shown, the ductal sleeve 350 can be positioned over balloon 378 so that ducts 368 lie between balloon 378 and wall 380 of artery 382. Ribs 366 appear to provide sufficient structural support to help keep ducts 368 open. (See column 14, lines 36-45). However, nothing in the embodiment of Figure 22 of Cox appears to teach, suggest, or disclose the claimed first and second inner diameters of the rotatable sheath.

Figure 8 of Cox appears to teach a perfusion adaptor 140 including a hollow member 142 and positioning member 143. (See column 9, lines 20-23). As is shown, perfusion adapter 140 includes a tapered distal region 144. (See column 9, lines 25-26). However, in contrast to the embodiment of Figure 22 of Cox, perfusion adaptor 140, which appears to be similar to perfusion adaptor 30 of Figure 2, is configured to be positioned between a balloon and the artery wall to permit a flow of blood past the balloon (see, for example, column 6, lines 44-47 and Figures 2A and 2B of Cox) and not around the balloon, as in Figure 22. As such, nowhere does Cox appear to teach or suggest a rotatable sheath disposed about at least a portion of an unexpanded balloon and having the claimed first and second inner diameters, as in claim 1. Further, there appears to be no reason to modify the ductal sleeve 350 of Figure 22 to include the tapered distal end, as in the perfusion adapter 140 of Figure 8. As can be seen in Figure 22, the ductal sleeve 350 is positioned over the balloon 378 using a positioning member 352 and moving the ductal sleeve 350 along the catheter shaft and fit over balloon 378. Applicants submit that there is simply no reason to modify ductal sleeve 350 with the tapered end of the perfusion adapter 140. As noted by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”.

(Emphasis added; see page 14 of the April 30, 2007 Decision and MPEP § 2141.) The Court further stated:

a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(See page 14 of the April 30, 2007 Decision.). The reason for the suggested modification provided in the Office Action is “to prevent atraumatic ends of the sheath for insertion and retraction in the blood vessel”. However, as noted above, ductal sleeve 350 is moved along the catheter shaft and, as such, has a guide. In contrast, perfusion adapter 140 appears to be advanced through the vessel without passing over a guide. As such, the ductal sleeve 350 does not appear to require the same atraumatic features as the perfusion adapter 140 and there appears to be no reason to modify the ductal sleeve 350 to include a tapered distal end. Accordingly, Applicants submit that the Office Action fails to provide the required articulated reasoning with some rational underpinning to establish a *prima facie* case of obviousness. Notably, the only apparent reason to modify Adams et al. in the manner suggested by the Office Action appears to come from Applicants’ own specification, which is clearly improper.

Further, Applicants submit that modifying the ductal sleeve 350 shown in Figure 22 with the tapered distal end of the perfusion adapter 140 would change the principle operation of the ductal sleeve 350, namely being moveable along the catheter shaft to a position over the balloon. The tapered distal end would appear to affect the ability of the ductal sleeve 350 to be moved over the balloon from the catheter shaft. Notably, MPEP § 2143.01 states “If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)”. Applicants submit that as the proposed modification would change the principle operation of the ductal sleeve of Cox and, as such, is not sufficient to render claim 1 *prima facie* obvious.

Further, the Office Action cites reference numeral 350 as teaching the claimed rotatable sheath and then asserts that bores 368 teach the claimed guidewire housing. This is not understood. As can be seen, claim 1 recites, “a guidewire housing, the guidewire housing

defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to an outer surface of the rotatable sheath". As shown in Figure 22, bores 368 are clearly provided on the interior of ductal sleeve 350 on not engaged to the outer surface. As such, nothing in Cox appears to teach, suggest, or disclose "a guidewire housing, the guidewire housing defining a guidewire lumen for passage of a guidewire therethrough, at least a portion of the guidewire housing being engaged to an outer surface of the rotatable sheath", as recited in claim 1. For at least these reasons, claim 1 is believed to be patentable over Cox. For similar reasons and others, claims 2, 5-9, and 31-38, which depend from claim 1 and include additional elements, are believed to be patentable over Cox.

In paragraph 7 of the Office Action, claims 3, 4, 15, 21, and 22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Wilson et al. (U.S. Patent No. 6,165,195). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Cox and nothing in Wilson et al. appears to remedy the noted shortcomings. Therefore, claims 3, 4, 15, 21, and 22, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Cox and Wilson et al.

In paragraph 8 of the Office Action, claims 24-29 and 51-61 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Wilson et al. (U.S. Patent No. 6,165,195), and further in view of Healy et al. (U.S. Patent No. 5,670,161). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Cox and Wilson et al. Nothing in Healy et al. appears to remedy the noted shortcomings of Cox and Wilson et al. Therefore, for at least these reasons, claims 24-29 and 51-61, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over the combination of Cox, Wilson et al., and Healy et al.

In paragraph 9 of the Office Action, claim 30 was rejected under 35 U.S.C. 103(a) as being unpatentable over Cox (U.S. Patent No. 5,257,974) in view of Lenker et al. (U.S. Patent No. 6,350,278). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 1 is believed to be patentable over Cox and nothing in Lenker et al. appears to remedy the noted shortcomings of Cox. Therefore, for at least these reasons, claim 30, which depends from claim 1 and includes additional distinguishing features, is believed to be

patentable over the combination of Cox and Lenker et al.

In paragraph 10 of the Office Action, claim 65 was rejected under 35 U.S.C. 103(a) as being unpatentable over Alba et al. (U.S. Patent No. 5,634,901) in view of Wilson et al. (U.S. Patent No. 6,165,195). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 62 is believed to be patentable over Alba et al. and nothing in Wilson et al. appears to remedy the noted shortcomings. Therefore, claim 65, which depends from claim 62 and includes additional distinguishing features, is believed to be patentable over Alba et al. and Wilson et al.

In paragraph 11 of the Office Action, claim 66 was rejected under 35 U.S.C. 103(a) as being unpatentable over Alba et al. (U.S. Patent No. 5,634,901) in view of Cox (U.S. Patent No. 5,257,974). After careful review, Applicant must respectfully traverse this rejection. As discussed previously, claim 62 is believed to be patentable over Alba et al. and nothing in Cox appears to remedy the noted shortcomings. Therefore, claim 66, which depends from claim 62 and includes additional distinguishing features, is believed to be patentable over Alba et al. and Wilson et al.

Newly Presented Claim

With this Amendment, Applicant has added newly presented claim 67. Applicants submit that nothing in the cited reference appear to disclose “wherein the first and second radially tapered ends of the rotatable sheath include a material having a higher hardness value than a portion of the rotatably sheath between the first and second radially tapered ends” as recited in claim 67. For at least these reasons, newly presented claim 67 is believed to be patentable over the cited references.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Application Serial No. 10/757,646
Response to Office Action dated October 6, 2009

Respectfully submitted,

Date: January 6, 2010



J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, Minnesota 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349